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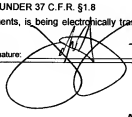


Attorney Docket No. 12730-11
Client Ref. No. PA-5327-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Thomas A. Osborne et al.	
Serial No. 10/642,513	Examiner: William H. Matthews
Filing Date: August 15, 2003	Group Art Unit No.: 3738
For Stent and Method of Forming a Stent with Integral Barbs	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In reply to the Final Office Action dated July 16, 2007, Applicants submit a request for pre-appeal review and the following remarks.

REMARKS

In the Claims:

Claims 45, 46, 48-50, 53, 58, and 60-62 are currently pending and are rejected under 35 USC § 102(b) as anticipated by U.S. Patent No. 5,800,526 ("Anderson"). Applicants respectfully request that the rejection be withdrawn because the Examiner has failed to establish a *prima facie* case of anticipation. In particular, Anderson does not teach or disclose a stent with 1) an integrally formed barb; 2) that points in a predetermined direction at an angle relative to a longitudinal axis of the stent; and 3) that is unbent with respect to the wire and is free of weakening due to bending.

Anderson describes only two ways to form a barb on a wire. First, the "barbs can be formed independently of the stent and subsequently attached to it by welding, brazing or another process with the equivalent effect." See Anderson; col. 6, lines 64-67. This is clearly a non-integral barb and such structures do not anticipate the claimed invention.

Anderson also describes barbs formed from a flat sheet of material, or a tube, "by chemically etching, laser cutting, or electronic discharge machining (EDM), and the like." See, *e.g.,* Anderson; col. 6, lines 60-63; col. 8, lines 52-54. Anderson discloses throughout the specification and in the drawings that such barbs are oriented in alignment with the longitudinal axis of the stent and not at an angle relative to a longitudinal axis of the stent, as recited in the rejected claims. See, *e.g.,* Anderson; Figs. 1-7, 15, and 17; col. 4, lines 13-16; col. 7, lines 47-50 ("[e]ach of the barbs . . . preferably faces in alignment with the common longitudinal axis when the multi-anchor stent is in an unexpanded configuration."). Thus, these unexpanded structures do not anticipate the claimed invention.

Furthermore, Anderson's expanded structures do not anticipate the claimed invention. In particular, although Anderson teaches that the barbs may be re-oriented when the stent is expanded, expansion of the Anderson stent results in 1) a barb that is bent with respect to the wire and weakened due to bending; and/or 2) a barb that points in an undetermined, rather than a predetermined direction.

The Examiner asserts that Anderson's barbs are not bent during expansion of the stent. See Final Office Action dated July 16, 2007; p. 2. This contention, however, is clearly refuted by the Anderson specification. First, Anderson teaches a pressure-expandable stent that necessarily experiences bending, distortion, and plastic deformation over the entire contour of the stent, including the connection between the barb and strut. Second, Anderson expressly teaches that expansion of the Anderson stent results in barbs that are oriented by bending or distorting the barbs. In particular, the specification teaches forming the stent using a step etching process "to remove portions of material so that the barbs will bend outwardly when the stent is expanded. In other words, . . . upon radial expansion of the stent, areas having less material will have a tendency to bend or distort." See Anderson; col. 9, lines 19-25. Emphasis added.

The Examiner states that Applicants "ha[ve] not shown how the barb itself would experience bending." See Advisory Action dated October 9, 2007 ("Advisory Action"). Applicants respectfully point out that the Examiner has the burden of providing evidence that Anderson discloses this claimed feature. The Examiner merely posits that "expansion or rotation of the stent struts does not require bending of the barbs." However, as explained above, Anderson expressly teaches that expansion of the stent struts does, in fact, bend the barbs. Moreover, the Examiner has not provided any evidence that an unbent barb is inherently disclosed in Anderson. Instead, the Examiner merely surmises that Anderson may include unbent barbs. However, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." MPEP 2112(IV). See also *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (rejecting the Board of Patent Appeals' finding of anticipation by inherency and holding that an analysis based merely on probability or possibility is insufficient to establish inherency.)

Even assuming, for the sake of argument, that Anderson teaches a stent with unbent integral barbs, Anderson does not teach such a stent with a barb that points in a predetermined direction as recited in the claimed invention. As explained in Applicants' specification, "it is preferable to orient the barbs 314 properly so that they will point in

the desired direction in relation to the longitudinal axis of the final stent shape." ¶205. The proper orientation is important to "ensure[] that the barbs 'catch' and engage the adjacent tissue." ¶206. Thus, predetermined orientation of the barb in the expanded configuration, as opposed to undetermined or random orientation, is an important aspect of the claimed invention.

In contrast, Anderson disparages stents where "exact placement of an anchoring stent . . . [is] critical for properly securing the stent," and provides a stent with "a plurality of barbs throughout the entire circumference of the stent . . . so that exact placement of the anchors is less critical." *See e.g.* Anderson; col. 3, lines 5-8; col. 3, lines 33-39. Emphasis added. Because Anderson's stent is pressure expandable, the stent may be expanded "to any number of larger diameters." See Anderson; col. 7, lines 41-44. Emphasis added. Moreover, "[t]he special expansion characteristics of the stent of the invention [allows] any portion of the stent that extends distally or proximally of the graft to continue to expand even when the graft has achieved its maximum cross-sectional dimension . . . ." See Anderson; col. 8, lines 25-31.

The Examiner cites column 12, lines 60-65 of Anderson, which states "[a]s is shown in FIG. 17, multiple barbs 142 also can be formed on the outer edges of the peaks and valleys of the cylindrical rings so that the barbs will be directed outwardly when the stent is expanded, to allow the stent to better grip whatever portion of the vasculature comes into contact with the stent." Advisory Action. Emphasis added. This statement further demonstrates the fact that Anderson discloses barbs that point in a random or undetermined direction, rather than in a predetermined direction. Because the expanded configuration of an Anderson stent is random and undetermined, and because the orientation of Anderson's barbs in the expanded configuration is affected by the manner and extent of expansion, the expanded orientation of Anderson's barb is random and undetermined and, therefore, not predetermined.

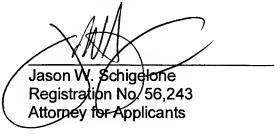
Finally, figures 16 and 17 of Anderson do not disclose a stent, as recited in claims 45 and 58. With regards to figure 16, the specification says only that barbs can be "formed in the surface of the cylindrical elements . . . to provide a sandpaper effect of raised, pointed, directional bumps of the surface of the stent." See Anderson; col. 12,

lines 52-60. With regards to figure 17, the specification states that "multiple barbs 142 also can be formed on the outer edges of the peaks and valleys of the cylindrical rings so that the barbs will be directed outwardly when the stent is expanded." See Anderson; col. 12, lines 60-65. As explained above, Anderson describes only two ways to form a barb: 1) welding, brazing, and the like; and 2) chemically etching, laser cutting, or electronic discharge machining. The first method results in non-integral barbs, and the second method results in barbs that are bent and weakened and/or barbs that do not point in a predetermined direction at an angle relative to a longitudinal axis of the stent. Accordingly, neither of these figures teaches or discloses all of the features recited in claims 45 and 58.

In order to anticipate under § 102, an asserted reference must teach or disclose each and every element of the claimed invention. MPEP § 2131. Because Anderson does not teach or disclose each and every structural feature of independent claims 45 and 58, it does not anticipate the claimed invention. Claims 46, 48-50, and 53 depend directly or indirectly from claim 45, and claims 60-62 depend directly or indirectly from claim 58. Accordingly, Anderson does not anticipate any of these claims.

The Examiner has failed to make a *prima facie* case of anticipation, and therefore, the rejection of claims 45, 46, 48-50, 53, 58, and 60-62 is improper. Applicants respectfully request that the rejection be withdrawn and that these claims be allowed to pass to issuance.

Respectfully submitted,



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